S/N 10/538,125

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

Applicant: CHAN ET AL. Examiner: UNKNOWN

Serial No.: 10/538,125 Group Art Unit: 1632

Filed: FEBRUARY 21, 2006 Docket No.: 11669.150USW2

Confirmation No.: 2225 Customer No.: 23552

Title: TRANSGENIC MICE EXPRESSING HUMAN CD20

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b))

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted before the mailing date of a first Office Action on-the-merits. Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

In accordance with 37 C.F.R. §1.98(a)(2), a copy of each document or other information listed on the enclosed Form 1449 is provided.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT & GOULD P.C.

P.O. Box 2903

Minneapolis, Minnesota 55402-0903

(612) 332-5300

Date: august 7, 2006

Katherine M. Kowalchyk
Reg. No. 36,848

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PATENT TRADEMARK OFFICE

FORM 1449*

INFORMATION DISCLOSURE STATEMENT

Docket Number 11669.150USW2 Application Number

Group Art Unit: 1632

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Applicant: CHAN ET AL.

Sheet 1 of 2

IN AN APPLICATION
(Use several sheets if necessary)

Filing Date: JUNE 7, 2005

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		FOR	EIGN PATENT DOCUM	MENTS	·		
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANS	LATION
						YES	NO
	1 452 093	09/01/1994	EP				
	WO 02/062946 A2	08/15/2002	PCT		<u> </u>		<u> </u>
	OTHER	DOCUMENTS	(Including Author, Title,	Date, Pertinent I	Pages, Etc.)		
	Arzoo et al., "Treatmen (rituximab)", <u>Ann. Rhei</u>		tibody mediated autoimm -924 (2002)	une disorders wi	th an anti-CD20 me	onoclonal ant	ibody
	Butler, "The Amplified ELISA: Principles of and Applications for the Comparative Quantitation of Class and Subclass Antibodies and the Distribution of Antibodies and Antigens in Biochemical Separates", Methods in Enzymology, 73:482-523 (1981)						
	Capecchi, "Altering the Genome by Homologous Recombination", Science, 244:1288-1292 (1989)						
	Capecchi, "The New Mouse Genetics: Altering the Genome by Gene Targeting", <u>T1G</u> , 5(3):70-76 (1989)						
	Davis et al., "Single-Agent Monoclonal Antibody Efficacy in Bulky Non-Hodgkin's Lymphoma: Results of a Phase II Trial Rituximab", Journal of Clinical Oncology, 17(6):1851-1857 (1999)						
	Fleit et al., "A Soluble I Inflammation", <u>Blood</u> ,		ıs Present ın Human Serui 8 (1992)	n and Other Bod	y Fluids and is Ele	vated at Sites	of
	Diagnosed Mantle-Cell	Lymphoma and	f Rituximab (Chimeric Ar Previously Treated Mantle linical Oncology, 18(2):31	e-Cell Lymphom			
	Gong et al., "Importance Immunology, 174(2):81		roenvironment and circula	tory dynamics in	B cell immunothe	rapy``, <u>Journa</u>	l of
	Gopal et al., "Clinical applications of anti-CD20 antibodies", J. Lab. Clin. Med., 134:445-450 (1999)						
	Kim et al., "Constructio (1996)	n and Character	zation of a Human Bacter	ial Artificial Chr	omosome Library"	Genomics, 3	34:213-21
	Mansour et al., "Disruption of the proto-oncogene <i>int-2</i> in mouse embryo-derived stem cells: a general strategy for targeting mutations to non-selectable genes", Nature, 336:348-352 (1988)						
			luble Serum CD16 (sCD16 ogy, 13(1):41-48 (1993)	b) Levels and Dis	seasc Stage in Patie	nts with Mul	tiple
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EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

Sheet 2 of 2

FORM 1449*

INFORMATION DISCLOSURE STATEMENT

IN AN APPLICATION

(Use

Docket Number: 11669.150USW2

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Applicant. CHAN ET AL.

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Protheroe et al., "Remission of inflammatory arthropathy in association with anti-CD20 therapy for non-Hodgkin's lymphoma", Rheumatology, 38:1150-1152 (1999) Shizuya et al., "Cloning and stable maintenance of 300-kilobase-pair fragments of human DNA in Escherichia coli using an Fractor-based vector", Proc. Natl. Acad. Sci. USA, 89:8794-8797 (1992) Solal-Celigny et al., "Rituximab as First-Line Treatment of Patients with Follicular Lymphoma (FL) and a Low-Burden Tumor: Clinical and Molecular Evaluation", Blood, 94(10):631a, Abstract #2802 (1999) Swiatek et al., "Perinatal lethality and defects in hindbrain development in mice homozygous for a targeted mutation of the zine finger gene *Krox20", Genes & Development, 7:2071-2084 (1993) Trape, "Rituximab chimeric anti-CD20 monoclonal antibody treatment for refractory hemolytic anemia in patients with lymphoproliferative disorders", Haematologicae, 88:232-2325 (2003) Van de Winkel et al., "Human IgG Fe receptor heterogeneity: molecular aspects and clinical implications". Immunology Today, 14(5):215-221 (1993) Weiner, "Monoclonal Antibody Therapy of Cancer", Seminars in Oncology, 26(5)(Suppl. 14):43-51 (1999) White et al., "Anti-CD20 monoclonal antibodies as novel treatments for non-Hodgkin's lymphoma", Pharm. Sci. Technol. Today, 2(3):95-101 (1999) Zelenetz et al., "Iodine 1131 Tositumomab for Patients with Transformed Low-Grade Non-Hodgkin's Lymphoma (NHL): Overall Clinical Trial Experience", Blood, 94(10):632a, Abstract 2806 (1999) GenBank Accession No. HO00387 dated February 22, 1996 GenBank Accession No. Me27394 dated July 15, 2006 GenBank Accession No. M27395 dated February 22, 1996 GenBank Accession No. NM_010188 dated June 12, 2006 GenBank Accession No. NM_0108509 dated July 16, 2006 GenBank Accession No. NM_000570 dated July 2, 2006 GenBank Accession No. NM_000570 dated July 2, 2006 GenBank Accession No. Z46222 dated April 18, 2005 GenBank Accession No. Z46222 dated April 18, 2005 GenBank Accession No. Z46223 dated March	quaternary structure'', Blood, 99(9):3256-3262 (2002)
Solal-Celigny et al., "Rituximab as First-Line Treatment Patients with Follicular Lymphoma (FL) and a Low-Burden Tumor: Clinical and Molecular Evaluation", Blood, 94(10):631a, Abstract #2802 (1999) Swiatek et al., "Perinatal lethality and defects in hindbrain development in mice homozygous for a targeted mutation of the zine finger gene Krox20", Genes & Development, 7:2071-2084 (1993) Trape, "Rituximab chimeric anti-CD20 monoclonal antibody treatment for refractory hemolytic anemia in patients with lymphoproliferative disorders", Haematologica, 88:223-225 (2003) Van de Winkel et al., "Human 1gG Fe receptor heterogeneity: molecular aspects and clinical implications". Immunology Today, 14(5):215-221 (1993) Weiner, "Monoclonal Antibody Therapy of Cancer", Seminars in Oncology, 26(5)(Suppl. 14):43-51 (1999) White et al., "Anti-CD20 monoclonal antibodies as novel treatments for non-Hodgkin's lymphoma", Pharm. Sci. Technol. Today, 2(3):95-101 (1999) Zelenetz et al., "Iodine I 131 Tositumomab for Patients with Transformed Low-Grade Non-Hodgkin's Lymphoma (NHL): Overall Clinical Trial Experience", Blood, 94(10):632a, Abstract 2806 (1999) GenBank Accession No. AH003353 dated February 22, 1996 GenBank Accession No. Mo2541 dated July 26, 1993 GenBank Accession No. P30273 dated July 15, 2006 GenBank Accession No. M27394 dated July 15, 1993 GenBank Accession No. M27395 dated February 22, 1996 GenBank Accession No. NM_0010188 dated June 12, 2006 GenBank Accession No. NM_000570 dated July 16, 2006 GenBank Accession No. NM_000570 dated July 16, 2006 GenBank Accession No. NM_000570 dated July 19, 2006 GenBank Accession No. Z46222 dated April 18, 2005 GenBank Accession No. Z46222 dated April 18, 2005 GenBank Accession No. Z46223 dated March 20, 1997	
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